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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,976	08/17/2001	Paul V. Haydock	018048-0011100US	7225

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,976	HAYDOCK ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/21/04

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed November 4, 2004 is acknowledged and has been entered. Claims have 41-47 and 91 have canceled. Claims 1-40 and 48-90 are pending. Upon further review of the claims, the indication of allowability of claims 1-40 and 48-90 is withdrawn in view of new grounds of rejections. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-19, 22-30, 38-40, 48-69, 71, 73-80, 88 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Gustafson et al (US 5,478,527, December 26, 1995). The preceding claims are sufficiently broad to encompass the following reference cited below. It is further noted that the instant prior art should have been cited in the previous Office Action. The examiner regrets any inadvertent inconvenience. Regarding claim 1-10, 15, 22-25, 49-59, 64 and 73-75, Gustafson et al teach a method for detecting a target analyte comprising contacting an insoluble support with a first reagent; removing the solid support from contact wit h the first reagent solution and contacting the solid support with a second reagent solution; wherein cross-

contamination of the second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material prior to contacting the solid support with the first reagent solution. Gustafson et al teach wherein the solid support is contacted with one or more intermediate solutions, wherein said intermediate solutions are one or more wash solutions. Gustafson et al further teach wherein the solid support is removed from containers containing the reagents, said container are selected from the group consisting of microwells, plates or a dipstick. Gustafson et al teach that the solid support is a silicon chip or wafer or microwell plate and further wherein the solid support comprises a capture regent which specifically binds to a target analyte (see col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 11-12, 14, 18-19, 28-30, 38-49, 60-61, 63, 68, 69, 73, 78-80, 88 and 89, Gustafson et al teach the method of claim 1 and 11, wherein a first reagent is TWEEN 20 or TRITON and the second reagent solution comprises a substrate which produces a detectable product when contacted with an enzyme linked to a signal reagent. This encompasses binding pairs such, as e.g., biotin, avidin, antibody, antibody fragment selected from the group consisting of Fab, Fab', or F(ab')2 fragments, hybrid antibody, protein A, protein G, chelating agent, enzyme, enzyme inhibitor, protein receptor, nucleotide hybridizing agent, antigen, hapten, lectin or a bacteria, virus, spore, parasite, yeast or fragment thereof or combinations thereof (col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 13, 16, 17, 48, 62, 65-67, Gustafson et al teach the method of claim 1, wherein the non-stick coating material is silane or polysilane polymers (col. 9, lines 4-26).

Regarding claim 21, 71 Gustafson et al teach wherein the capture reagent is attached to the solid support prior to the contacting the test sample with the solid support (col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 26, 27, 76, 77, Gustafson et al teach wherein the capture reagents is covalently attached or non-covalently attached to the solid support (col. 7, lines 16 to col. 8, line 11). Therefore, Gustafson et al meets the limitation of the claims recited above.

Claim Rejections - 35 USC § 102

5. Claims 1, 10, 13-17, 20-22, 26, 27 29, 31-36, 38-40 48-50, 62-67, 70-72, 81-87 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al (US 5,587,128, December 24, 1996). Regarding claims 1, 10, 13-17, 20-22 29, 31-32, 48-50, 62, 64-67, 70-72, Wilding et al teach a method of reducing cross-contamination of an assay reagent solution, the method comprising: contacting a solid support with a first reagent solution; and contacting the solid support with a second reagent solution; contacting the solid support with a second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material prior to or subsequent to contacting the solid support with the first reagent solution, wherein the non-stick coating material is selected from the group consisting of silane, dimethlychlorosilane, hexamethyldisilazane or trimethylchlorosilane (col. 5, lines 27-39). Widling et al teach wherein the solid support comprises a capture reagent that binds to a target analyte, wherein said capture reagent is attached to the solid support prior to or simultaneously with or after contacting the test sample with the solid support and wherein the target analyte comprises a polynucleotide (e.g., DNA or RNA) and wherein the capture reagent comprises a polynucleotide probe or antibody (col. 9, lines 15-53 and col. 19, lines 38-46).

Regarding claims 26 and 27, Wilding et al teach that composition may be attached to the solid support covalently or non-covalently (col. 5, lines 45-48).

Regarding claim 33 and 63, Wilding et al teach wherein the signal reagent comprises a detectable label attached to an oligonucleotide which hybridizes to the polynucleotide (col. 20, lines 13-23).

Regarding claims 35, 36, 85 and 86, Wilding et al teach wherein the polynucleotide is amplified prior to contacting the sample with the capture reagent, wherein said amplified procedure is selected from the group consisting of polymerase chain reaction, ligase chain reaction, strand displacement amplification (col. 6, lines 40-67)

Regarding claims 38-40, 83, 84, 88-90 Wilding et al teach wherein the capture agent comprises and antibody which binds to the target analyte or an oligonucleotide which binds to the target analyte. Wilding et al additionally teach wherein the signal reagent may be an antibody which binds to the target analyte and wherein the signal reagent comprises a detectable label which may be attached to an oligonucleotide or antibody (col. 19, line 38 to col. 20, line 29). Therefore, Wilding et al meet the limitations of the claims recited above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 37 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al as previously applied above in view of Van Ness (Nucleic Acids Research, Vol. 19, No. 19, pages 5143-5151, 1991). Regarding claim 37, Gustafson et al teach a method for reducing cross-contamination and detecting an analyte in a sample using a solid support as previously discussed above. Gustafson teach wherein in the method, the solid support is contacted with a denaturant wherein said denaturant is a detergent. Gustafson et al differs from the instant invention in that the reference does not teach wherein the denaturant is a chaotropic solution selected from the group consisting of guanidine, sodium thiocyanate, urea, and lithium tetrachloroacetate. In a general teaching, Van Ness discloses the advantages of using chaotropic solution in nucleic acid diagnostic assays which are in a sandwich assay format (utilization of solid support). Van Ness teaches that chaotroptic solution, such as e.g., lithium tichloroacetate, guanidinium chloride, guanidinium thiocyanate, sodium thiocyanate, rubidium trichloroacetate, sodium perchlorate, potassium iodide or cesium trifluoroacetate (page 5144, first paragraph of col. 1), are significantly advantageous in terms of reducing background in a sandwich assay format (pages 5148 to page 5149, entire section entitled "Reduction of

background in a sandwich Assay format using TCA-based hybridization solution"; see also introduction on page 5143). Therefore, in view of the foregoing, one of ordinary skill in the art would have been motivated to have modified the method of Gustafson et al to encompass the use of a chaotropic agent such as guanidine or lithium tetrachloracetate as the denaturant instead of a detergent as used by Gustafson in the detection method for the advantages of reducing background as taught by Van Ness.

Conclusion

9. Claims 1-89 are not allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CYNTHIA WILDER
PATENT EXAMINER